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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/742,343	12/19/2003	Stephen Gara	THR-5005 USNP	6427
27777	7590	10/18/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			WIEST, PHILIP R	
			ART UNIT	PAPER NUMBER
			3761	
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			10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/742,343	GARA, STEPHEN	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In the amendment filed 8/9/07 the amendments to claims 1 and 12 are acknowledged. Claims 1-21 are currently pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (4,737,140). Lee et al. (hereafter Lee) discloses a U.V. light assembly for use with an extracorporeal blood separation assembly. The U.V. light assembly is comprised of a first and second plates fit together to define a thin cavity to receive blood or separated blood components. The plates comprise identical boundry portions that line up to crease a boundary defining a series of flow paths. The cavity is separated into a serpentine path by multiple, evenly spaced dividers. The chamber comprises a first port 209 and a second port 210 that are in fluid communication at opposite ends of the chamber. The chamber further comprises seven partitions (six middle partitions 503, and one side partition 504 separating channel 511). Regarding the requirement that the

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flow of fluid through the chamber is assisted by gravity, the device is fully capable of being arranged such that gravity assists fluid flow through the chamber 512 from the inlet port 209 to the outlet port 210. Lee teaches that the device may be made of polycarbonate and is transparent to UVA rays, which are in the wavelength range between 320 nm and 400 nm. Lee also teaches that a photoactivating agent, such as 8-methoxy psoralen (8 MOP), may be added to the blood or blood component (Column 7, Lines 12-14). It is also taught by Lee that the separated component from the blood can be leukocytes or a buffy coat. The chamber is translucent, such that both sides are susceptible to irradiation at the same time (see Figure 3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrassy (US 3,022,781) in view of Lee (US 4,737,140).

6. With respect to Claims 1, 2, and 5-21, Andrassy discloses a device for conveying solar energy to a fluid (i.e. an irradiation chamber) comprising two identical plates that are molded together at raised boundary portions (see Figure 3) in order to create a serpentine chamber, the flow of fluid through the chamber

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being assisted by gravity (see Figure 1). The serpentine chamber has an inlet port 18 and an outlet port 19 that are both in contact with both plates, said ports being in fluid communication by the channels 17 of the chamber. The first and second surfaces are subject to irradiation at the same time. Andrassy, however, does not disclose that the irradiation chamber is made of rigid polycarbonate or acrylic, or that the chamber is used to treat blood before returning it to the body.

7. Lee discloses an irradiation chamber and method of treating blood, wherein the chamber is made of two rigid, polycarbonate plates that form flow channels having a thickness of 0.04 inches. It is well established in the art that 0.04 inch thick polycarbonate channels are ideal for the irradiation of blood (Column 6, Lines 14-22 and Column 10, Lines 49-51). Additionally, Lee teaches that a photoactivating agent, such as 8-methoxy psoralen (8 MOP), may be added to the blood or blood component (Column 7, Lines 12-14), and the leukocytes or a buffy coat can be separated from the blood.

8. Andrassy clearly discloses the irradiation of fluids using a serpentine flow chamber made of two identical outer plates that have been molded together, and Lee clearly discloses the use of a similar serpentine chamber to irradiate blood in the manner disclosed by applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the irradiation chamber of Andrassy with the rigid, polycarbonate material, 0.04 inch thick channels, and blood treatment method of Lee in order to provide optimal conditions for irradiating blood.

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9. With respect to Claims 3 and 4, Andrassy in view of Lee does not specifically disclose that the chamber comprises exactly 7 partitions. Lee further discloses that the chamber may comprise seven partitions (six middle partitions 503, and one side partition 504 separating channel 511). The number of partitions, however, is irrelevant because the exact number of channels has no bearing on the effectiveness of the device as long as the amount of time taken for the blood to move through the channel is constant. Furthermore, the exact amount of irradiation required is taught by Lee, and the flowrate may be altered using a pump to ensure that blood receives the optimal length of irradiation exposure. Therefore, the mere number of partitions and channels has no bearing on the functionality of the chamber. Mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEP § 2144.04.

Response to Arguments

10. Applicant's arguments filed 8/9/07 have been fully considered but they are not persuasive.

11. Applicant argues that the device of Lee does not disclose an arrangement that can allow for gravity assistance throughout the course of the flow of fluids, but rather must use a means that assists the flow through the chamber. The argument is based on the way in which the inlets and outlets are arranged. This argument is not found to be persuasive.

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12. Applicant recites that the device has a port "arranged such that during use, the flow of fluid through out said chamber is assisted by gravity" which is a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *If the prior art structure is capable of performing the intended use, then it meets the claim.* The chamber 512 of Lee is capable of being positioned such that the inlet 209 is higher than the outlet 210 to allow for gravity to act upon the fluid. The device is a stand-alone unit and it may be positioned in a manner to allow for gravity to act upon the fluids. There is no specific or distinct structural element recited in the application claims that distinguishes the invention from the chamber of Lee. Additionally, even in the upright position (as shown in Figure 4), fluid inlet 501 is located above fluid outlet 502, and at least one downward flow path is present. Therefore, fluid flow through the system is *assisted* (i.e. affected, but not fully controlled by) gravity. Even if the device is positioned as shown in figure 5 of Lee, gravity still *assists* the flow of fluid through the device.

13. Applicant also argues that the device of Lee is defined by male and female sections of the plate surfaces, said sections having different molding requirements. This argument is also not found to be persuasive.

Although Lee does in fact disclose male and female plate sections, these sections still comprise a series of male and female parts, and are therefore raised at the boundary portions of the chamber (the female portion is raised at the edge of the boundary portion surrounding the female grooves). The raised

portions of Lee therefore *contact* each other, as claimed by applicant. Applicant does not specifically claim that the raised portions or the plates must be *molded* in a certain way. Even of the specific method of bonding the plates together was claimed, a product-by-process rejection would be issued, as the final product would function identically to the prior art. See MPEP 2113.

14. Applicant argues that molding the top and bottom plates such that only the raised portions are molded has added benefits such as reducing flash and enhancing irradiation, the examiner requests evidence of these. *If applicant amends the claims such that the raised portions are molded together (instead of simply contacting each other), the examiner requests evidence this type of molding truly has the claimed effects.*

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571) 272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
10/3/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

